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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,459	09/30/2003	Paul J. Bobrowski	PHMC0745-022	7541
26948	7590	05/18/2006		
ELLIS & VENABLE, PC 101 NORTH FIRST AVE. SUITE 1875 PHOENIX, AZ 85003			EXAMINER SHAH, CHIRAG V	
			ART UNIT 1761	PAPER NUMBER

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/676,459	Applicant(s) BOBROWSKI, PAUL J.	
	Examiner Chirag V. Shah	Art Unit 1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09/30/2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>09/30/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-23 are rejected under 35 U.S.C. 112, first paragraph, because the best mode contemplated by the inventor has not been disclosed. Evidence of concealment of the best mode is based upon a lack of description and clarity regarding the meaning of "pharmaceutical dosage unit" and the claimed benefits are not enabling to one of ordinary skill or adequately described in the specification.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "pharmaceutical dosage unit" is ambiguous and vague. Please make appropriate corrections.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 1, 3-5, 7, 10, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Zheng et al (US 6267995 B1).

Zheng et al. teaches combining plant material from the Family Brassicaceae, specifically *Lepidium Meyenii* roots or MACA for pharmaceutical applications (abstract, col. 1, lines 1-12) disclosure is made to adding methanol (col.6, lines 1-6), agitating the mixture and filtering the combination through an elution process (col. 4, lines 20-45 and col.5, lines 55-65) with higher polar components and lower lipidic components (col.5 lines 25-35) and evaporating the alcohol (col. 4, lines 40-51) to resolve the polar components.

Addressing claims 10, 13 and 14 Zheng et al., discloses a process that includes heating, evaporation, homogenizing mixture, spray drying, vacuum drying and comminuting or macerating the *Lepidium Meyenii* roots or MACA in an aqueous medium, before exposure to an alcohol solvent (see col. 4, lines 20-48 and col. 8, lines 55-67 and col. 9, line 1-15).

Claims 11 and 12 require a filtering process with decrease in pore size and adding an alcohol solvent. Zheng teaches use of a fractionated gradient column with alcohol elution, see col. 5, lines 15-55 and col. 2, lines 20-45)

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Based on the above disclosure, Zheng clearly anticipates the above cited claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 2,6, 8,9, 15-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zheng et al (US 6267995 B1).

Addressing claim 2, Zheng et al does not specifically mention that the plant material is the "hypocotyls" portion of the root. However, Zheng does specify the "sterol" portion, which Zheng claims are the active portion of the plant to derive the extract. At this time no patentable distinction is seen from Zheng's disclosure and the claimed limitation of "hypocotyls".

Therefore, it would be obvious to one skilled in the art to obtain the "extract" portion from the part of the root where the active ingredient is likely localized.

Claim 6 requires moisture content of 20% of the washed, dried and ground plant material. As stated above, Zheng discloses the method steps claimed by applicant, thus it would be obvious to one of ordinary skill to allow a drying time to achieve the claimed range of 1-20% from the disclosure of Zheng et al at col. 4, lines 20-48.

Claim 8 requires 1:4 ratio of plant material and alcohol. Zheng teaches adding an alcohol-water mixture in the range of 70-95% (see col. 9, lines 30-37). However, specific teaching of a ratio of 1:4 is not made. Nonetheless, it would have been obvious to one of ordinary skill to mixture the material at a given ratio to achieve the desired result.

Claim 9 requires an "agitation" step. A homogenizer as taught by Zheng, is seen to meet this limitation (col. 8, lines 55-67). Therefore, it would have been obvious to one of ordinary skill to mix or agitate the composition when adding alcohol solvent to the plant material.

Claim 15 further requires that the polar components be concentrated and the lipidic components reduced. The process disclosed by Zheng teaches separation of polar material and with a gradient column or RPLC, it would be obvious to one of ordinary skill to manipulate the process to yield more concentrated polar compounds, Zheng states " it will be apparent to one skilled in the art that the identity and amounts of constituents of second *Lepidium* compositions made by this process can be varied. " (col. 7, lines 40-60).

Claims 16-23 disclose a "pharmaceutical dosage unit" with claimed benefits to fish and addition of additives. Please note that these claims are under a 112 first paragraph and second paragraph rejection for indefiniteness. Although Zheng does not specifically address the benefits of the present claimed limitations, Zheng does teach the same compound/extract as presently claimed and does disclose pharmaceutical application with pharmacological activity on

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animals (col. 8 lines 20-60). Claim 23 further requires the form of the compound be in a "pellet" or "fish meal". Zheng does teach making the compound palatable to animals in "oral dosage forms" (col. 8, lines 45-55) thus it would have been obvious to one of ordinary skill to apply this teaching to non-specified animal foods, like fish meal. It is the examiner's position that the compound may inherently have the claimed benefits and thus would have been obvious to one skilled in the art to market and commercialize such uses of the claimed compound. Mixing the compound to cereal or adding vitamins would be obvious to one skilled in the art. Therefore, designing or applying the extract/compound to forms digestible or beneficial to animals would have been obvious to one of ordinary skill from the teaching of Zheng et al., especially to derive the commercial benefits of this product.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chirag V. Shah whose telephone number is 571-272-2766. The examiner can normally be reached on Mon-Friday 6:00am to 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chirag V. Shah

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May 15, 2006

CVS



H. Pratt
HELEN PRATT
PRIMARY EXAMINER